IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC, *Plaintiffs*, v. EAGLE PHARMACEUTICALS INC., *Defendant*.	C.A. No. 18-823-CFC-JLH
PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC, *Plaintiffs*, v. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, et al., *Defendants*.	C.A. No. 18-2032-CFC-CJB

PAR'S POST-TRIAL BRIEF REGARDING
VALIDITY AND ENFORCEABILITY OF THE '209 AND '785 PATENTS

Dated: July 28, 2021

OF COUNSEL:

Martin J. Black
Sharon K. Gagliardi
Brian M. Goldberg

Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
FARNAN LLP
919 North Market St.
12th Floor
Wilmington, DE 19801
Tel: 302-777-0300

Luke M. Reilly
Daniel R. Roberts
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104
Tel: (215) 994-4000
martin.black@dechert.com
sharon.gagliardi@dechert.com
brian.goldberg@dechert.com
luke.reilly@dechert.com
daniel.roberts@dechert.com

Robert D. Rhoad
DECHERT LLP
502 Carnegie Center, Suite 104
Princeton, NJ 08540-7814
Tel: (609) 955-3200
robert.rhoad@dechert.com

Jonathan D. J. Loeb, Ph.D
DECHERT LLP
2400 W. El Camino Real, Suite 700
Mountain View, CA 94040-1499
Tel: (650) 813-4995
jonathan.loeb@dechert.com

Blake B. Greene
DECHERT LLP
300 W. 6th Street, Suite 2010
Austin, TX 78701
Tel: (512) 394-3000
blake.greene@dechert.com

Fax: 320-777-0301
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Plaintiffs Par Pharmaceuti
Inc., Par Sterile Products, LLC, and End
Par Innovation Company, LLC

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

TABLE OF ABBREVIATIONS

Abbreviation	Description
DCOL	Defendants' Proposed Conclusions of Law on Invalidity and Unenforceability
FOF	Par's Proposed Findings of Fact Regarding Validity and Enforceability of the '209 and '785 Patents

I. INTRODUCTION

Defendants' sole invalidity attack is obviousness in light of Original Vasostrict. They chose not to advance a standard obviousness case based on the *Graham* factors, motivation to combine the art, and reasonable expectation of success. Rather, they put all their eggs in one basket, arguing for a presumption of obviousness in light of Original Vasostrict's pH, which they say "abuts" the claimed inventions. The Congressionally-mandated presumption of validity in §282 and the Supreme Court's obviousness jurisprudence cannot be dispatched so easily, and Defendants' failure to present the required obviousness analysis is fatal. Additionally, there is strong evidence under the *Graham* factors supporting the Examiner's finding of patentability; certainly, the trial record contains no clear and convincing evidence of obviousness.

There is nothing equitable in Defendants' inequitable conduct case. After finding no fault with the prosecution of the patents-in-suit, Defendants turned a litigation-eye to prior applications, eventually focusing on two statements by Dr. Kannan and magnifying them out of all proportion. The first is a quibble over the meaning of the phrase "subject matter" in patent law, with Defendants taking the incongruous view that Dr. Kannan represented he had invented vasopressin itself. The second involves nit-picking over the presentation of data, which even Dr. Chyall conceded made no difference in the end and showed no evidence of

deceitful intent. In neither case did Defendants connect the dots to the patents-in-suit by showing a necessary relation to the alleged misconduct. In short, this is just the sort of rickety inequitable conduct case *Therasense* sought to discourage. Plainly, there is no just cause in equity to render a capital sentence against the Asserted Patents.

II. DEFENDANTS FAILED TO PROVE OBVIOUSNESS

A. Law of Obviousness

Par is entitled to the statutory presumption of validity that attaches to all issued patents under 35 U.S.C. §282. Accordingly, to establish obviousness, Defendants must prove by clear and convincing evidence that the differences between the claimed subject matter and the prior art are such that the claimed invention would have been obvious to a POSA on the priority date. 35 U.S.C. §103; *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 100 (2011). To assess obviousness, courts consider: (i) the scope and content of the prior art; (ii) the differences between the prior art and the claims; (iii) the level of ordinary skill in the art; and (iv) secondary considerations of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

Defendants seek to avoid their burden by invoking *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) and other appeals from PTO and PTAB decisions, which apply a different burden of proof. They point to no decision in an

infringement action conducting the sort of short-form invalidity analysis Defendants proffer here—identifying art "abutting" the claims, then shifting the burden to the patentee. Such a rule would be inconsistent with the statutory presumption of validity legislated by Congress and the Supreme Court's *Graham* analysis. Even in PTAB cases, "the language employed in our overlapping range cases does not shift the burden of persuasion to the patentee to prove nonobviousness…" *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1008 (Fed. Cir. 2018).

B. Defendants Are Not Entitled to a Presumption of Obviousness

Even if the Court were to entertain Defendants' analogy to *In re Peterson*, no presumption would apply here.

First, as to '209 claims 5 and 8, no prior art Original Vasostrict product possessed the claimed impurity levels or pH. DCOL,6-7; FOF204-205, 231-232, 239-240, 254. Because the impurity limitations and the claimed pH range are missing, there can be no presumption under *In re Peterson*—unless we are now to accept a "doubly abutting" theory.[1]

[1] The Court was presented with a related issue in *Tris Pharma, Inc. v. Actavis Labs. FL, Inc.*, 503 F.Supp.3d 183, 203 (D. Del. 2020), in which it properly refused to apply a presumption against the patent holder.

Second, Defendants ignore the Examiner's findings during prosecution, which are entitled to significant weight. She allowed the claims over the PPC label, which taught a pH range (2.5-4.5) that entirely subsumes the claimed pH 3.7-3.9 range and the Original Vasostrict pH 3.4-3.6 range. FOF277. Defendants now ask the Court to erect a ***presumption of invalidity*** in relation to a range the Examiner considered. That cannot be the law.

Third, there are only a handful of abutting-range cases, and none like this. Defendants read *In re Peterson* to mean that a presumption would apply if a POSA would have expected the 3.4-3.6 and 3.7-3.9 ranges to have the "same properties." DCOL,4 (citing 315 F.3d at 1329). But as discussed below, the evidence shows that a POSA ***would not*** have expected the ranges to have the same stability properties.[2] FOF249-252, 260-269. Accordingly, even under Defendants' view of the law, application of the *In re Peterson* presumption would be inappropriate.

C. Defendants Failed to Address the Elements of Obviousness

Whether considered under a traditional §103 analysis where the challenger bears the burden of proof, or under the misperceived framework presented by the

[2] Defendants also argue that a presumption attaches because a POSA would expect pH 3.64 and 3.65 to behave the same. While Defendants assert Dr. Kirsch supported sameness, he testified just the opposite: "Q. [W]hat you've suggested here is that a product with 3.64 and one with 3.65, you're opining that those are expected to have different properties? A. Yes." Tr. 850:17-21; FOF253, 274.

Defendants, there was substantial unrebutted evidence presented supporting validity.[3] Notwithstanding Defendants' decision to eschew the *Graham* factors, we present the analysis below.

1. The Prior Art as a Whole Teaches Away

Defendants' obviousness attack is sheer hindsight, focusing on a specific lot or two of Original Vasostrict out of many without providing any reason for the selection. FOF280, 288. One "cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Ecolochem, Inc. v. S. California Edison Co.*, 227 F.3d 1361, 1371 (Fed. Cir. 2000). Instead, "prior art must be considered as a whole for what it teaches." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1166 (Fed. Cir. 2006). Here, the prior art as a whole taught that pH 3.4-3.6 was the optimal range for stability and discouraged POSAs from using the claimed pH 3.7-3.9 range. FOF196, 260-271.

[3] When a prima facie case is demonstrated for overlapping ranges, the patentee may "come forward with evidence of criticality, teaching away, unexpected results, or other pertinent evidence of nonobviousness." *DuPont*, 904 F.3d at 1006-1007 (citations omitted). The Court "then assesses that evidence, along with all other evidence of record, to determine whether [Defendants have] carried [their] burden of persuasion to prove that the claimed range was obvious." *Id.*

Bi 2000 taught that increasing the pH of vasopressin formulations above 3.4 would decrease stability. FOF260-262.[4] Similarly, the FDA Biopharmaceutics and Chemistry Reviews clearly indicated to POSAs that leaving the optimal pH 3.4-3.6 range would decrease stability:

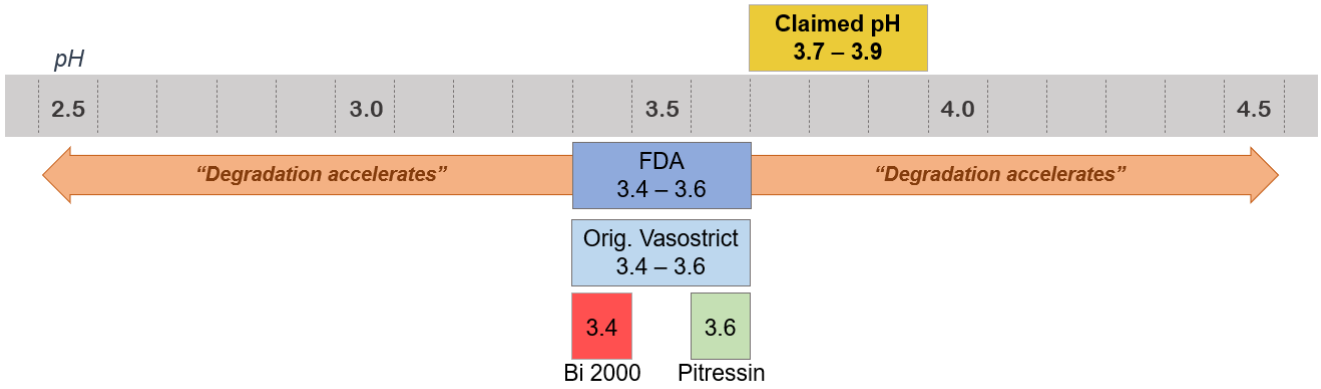
> The pH of the formulation is critical because at pHs below 3.4 and above 3.6, degradation of vasopressin accelerates, with the degradation rate increasing as the pH deviates further from the pH 3.4-3.6 range.

PTX-146 at EAGLEVAS0014353; PTX-309 at PAR-VASO_0238742 (similar); FOF263-269. Dr. Park admitted that a POSA would have looked to the FDA publications. FOF264. Defendants' scattershot attacks (DCOL,17) against these reliable FDA statements are unavailing. FOF272.

In fact, there was nothing publicly known that would have directed a POSA towards the claimed pH range. FOF271. Defendants' hindsight response (DCOL,16) is to argue the POSA would have relied on a cherry-picked, expired batch of Pitressin for which the pH was not public (FOF280, 283) or a Lithuanian animal-vasopressin patent that would have been of no help in developing a synthetic vasopressin product (FOF278-279).

[4] Without any testimony, Defendants assert that Bi 2000 would not teach away because it is limited to phosphate buffers, but Dr. Kirsch explained that its teachings are not so limited. FOF273.

The prior art, therefore, taught away from the claimed range:



PDX6-8; FOF268-271.

Such teaching away evidence is highly significant. "An inference of nonobviousness is especially strong where the prior art's teachings undermine the very reason being proffered as to why a [POSA] would have combined the known elements." *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir. 2009). Indeed, just last week, the Federal Circuit issued an on-point decision. *Chemours Co. FC, LLC v. Daikin Indus*., 2021 WL 3085514 at *4-5 (Fed. Cir. July 22, 2021). There, a reference ("Kaulbach") taught a broad range encompassing the claimed range, as well as a specific preferred value just below the claimed range. The reference expressly focused on the advantages of the slightly lower value, but the PTAB concluded it would have been obvious to increase the value anyway. The Federal Circuit reversed the PTAB, holding that

Kaulbach's statements taught away from using the claimed range, and that there was no motivation to move into the range.

The facts are more compelling here. The prior art's teaching that degradation accelerates at pHs above 3.6 negates any motivation to change the pH to optimize stability. As a result, a POSA would have expected vasopressin formulations with pH 3.7-3.9 to provide inferior, not superior, stability performance to formulations with pH 3.4-3.6.[5] FOF268. As in *Chemours*, such strong teaching away evidence is dispositive.

2. Differences Between the Asserted Claims and Original Vasostrict

The published pH of Original Vasostrict was 3.4-3.6. A POSA would have believed that to be the ideal pH range. FOF195-196.

Undeterred, Defendants presented a hindsight-inspired, mix-and-match theory using different Original Vasostrict products and documents: (1) the Original Vasostrict label; (2) one registration batch (310571); and (3) two commercial lots (788435 and 788436). DCOL,4-8.

[5] For reasons addressed in the criticality section below, Defendants' "commensurate with the scope" argument is without merit. *MeadWestVaco Corp. v. Rexam Beauty and Closures, Inc*., 731 F.3d 1258, 1264 (Fed. Cir. 2013), is inapposite because the teaching away evidence was specifically directed to an unclaimed feature (fluoropolymer in a fragrance product). Here, the teaching away in Bi 2000 and the FDA publications went directly to a claimed feature, pH.

Defendants' selective reliance on Par confidential information about Original Vasostrict is not how a POSA would have gone about evaluating the vasopressin art. A POSA would have known the published range of 3.4-3.6 but not the specific pH values of any Original Vasostrict lot. FOF280, 288. Moreover, nothing would have directed a POSA to Original Vasostrict lots 788435 or 788436 among all the lots that were sold. *Id.* The impurities within vasopressin products were unknown, so there was no disclosure of the claimed impurity levels. FOF200, 292. Importantly, there was no evidence of any Original Vasostrict product that concurrently met the pH and impurity limitations of the Asserted Claims. FOF201-203, 209, 220, 223, 229, 241-244.

Additional gaps in Defendants' evidence can be seen by taking each in turn:

Original Vasostrict Label: The label (DTX-132.4-5) taught Original Vasostrict was "adjusted with acetic acid to pH 3.4-3.6" (outside the claimed range) and provided no disclosure about impurity levels. FOF202-203.[6]

Lot 788435: Defendants argue this lot met the impurity limitations after 12 months storage and had "an abutting pH of 3.6." DCOL,7. Defendants imply the pH might have been as high as 3.64, but there is no such evidence, and the actual

[6] Contrary to Defendants' assertion (DCOL,8), the patents do not state Original Vasostrict's pH was "about" 3.4-3.6, nor did Dr. Kirsch agree "about 3.6" included pHs above 3.64. FOF256-257.

pH might have been as low as 3.55. FOF232, 255. Accordingly, Defendants have no clear and convincing evidence that Original Vasostrict with a pH of 3.64 met the other limitations of the Asserted Claims. *See* DCOL,5-7.

Lot 788436: There is no evidence of the pH or impurity levels of lot 788436 when on sale or in public use. FOF230-231. Thus, Defendants failed to prove lot 788436 satisfied these limitations at a time when it qualified as prior art. *Id.* Defendants also admit that, at the "initial" time, lot 788436 did not contain the impurities required by '209 claims 1, 4, and 6-8 or '785 claims 1, 5, and 8. DCOL,6-7; FOF225-228.

Registration Batch 310571: Batch 310571 was never on sale or in public use and, therefore, is not prior art. FOF205. Additionally, at the initial and three-month measurements cited by Defendants, it had a pH of 3.5, which does not "abut" the claimed range. *See* FOF210-214. Batch 310571 had a single pH reading of 3.8 at 18 months, but the impurities then were well outside the claimed ranges. FOF206-208, 215-219.

A POSA would have had no guidance or motivation to choose these lots among the many. What this shows though is that Defendants' obviousness defense is wholly reliant on blatant hindsight and fails, therefore as a matter of law: "Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the

patented invention." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998).[7]

3. No Motivation to Combine

To protect against "distortion caused by hindsight bias," there must be "a reason that would have prompted a [POSA] to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 418, 421 (2007). Here, Defendants presented no evidence that there would have been a motivation to combine or modify the prior art to achieve the claimed inventions. FOF259. The record shows the opposite—that vasopressin products were stable, safe, and efficacious, such that there was no motivation to improve their stability. FOF189, 192, 286-287. There was also no motivation to lower impurities to the claimed levels (FOF287), or to modify the specific lots Defendants identified (FOF280, 288). And, even if a POSA were motivated to improve vasopressin

[7] Relying on purportedly inherent pH and impurity properties specific to an individual, cherry-picked lot is an improper foundation for an obviousness analysis. Defendants' case (DCOL,6-7), *Abbott Lab'ys vs. Geneva Pharms*., 182 F.3d 1315, 1319 (Fed. Cir. 1999), addresses inherent anticipation, not obviousness. "[T]he use of inherency in the context of obviousness must be carefully circumscribed because that which may be inherent is not necessarily known and that which is unknown cannot be obvious." *Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A. DE C.V.*, 865 F.3d 1348, 1354-55 (Fed. Cir. 2017) (internal quotation marks omitted). It is unsurprising, therefore, that Defendants have failed to cite to any case in which a presumption of obviousness was based on the selection of one batch of a prior art product from among many based on a unique, undisclosed property.

stability, as discussed above, the art taught the claimed pH range would not have been fruitful, thereby negating any motivation. "[A] reference that 'teaches away' from a given combination may negate a motivation to modify the prior art to meet the claimed invention." *Ormco Corp. v. AlignTech., Inc.*, 463 F.3d 1299, 1308 (Fed. Cir. 2006).

4. No Reasonable Expectation of Success

Defendants failed to establish there would have been a reasonable expectation of success in achieving the claimed inventions. FOF289. Defendants admitted they provided no expert testimony on the subject. *Id*. The only expert to testify on the topic, Dr. Kirsch, demonstrated there was neither a reasonable expectation that the claimed pH 3.7-3.9 values would have improved stability, nor would a POSA have reasonably expected to achieve the specific impurity levels claimed. FOF290-291.

Given the teaching away from the claimed pH range, the significant differences between the Asserted Claims and Original Vasostrict, the lack of a motivation to make the claimed inventions, and the lack of a reasonable expectation of success, Defendants failed to prove obviousness by clear and convincing evidence. FOF258.

5. Par Presented Substantial Evidence of Criticality and Unexpected Results

a. The Evidence

While not required to rebut Defendants' flawed invalidity case, Par presented substantial evidence that the pH 3.7-3.9 range was critical and yielded unexpected results. FOF297-298.

First, the inventors presented data supporting criticality of the claimed 3.7-3.9 range over the prior art pH 2.5-4.5 range of the PPC label. FOF277, 299-304. That is far closer prior art than the Defendants are relying on now, as it completely subsumes, rather than "abuts," the claimed range.

Second, Dr. Kirsch performed an independent statistical analysis on the inventors' data comparing the claimed pH 3.7-3.9 to the entire 2.5-4.5 range and found a statistically significant difference. FOF305-306, 310, 312, 314. As Dr. Kirsch explained with the following demonstrative, the data in the inventors' declarations shows that each of pH 3.7, 3.8, and 3.9 exhibit statistically superior stability to Original Vasostrict's pH 3.4, 3.5, and 3.6:

pH	Change in Impurities 40°C	Mean difference compared to pH 3.8 value	Statistically Significant (mean difference > 0.28%)		
			Compared to 3.7	Compared to 3.8	Compared to 3.9
2.5	16.93 ± 0.14	16.05	Yes	Yes	Yes
2.6	13.36 ± 0.14	12.48	Yes	Yes	Yes
2.7	11.2 ± 0.14	10.32	Yes	Yes	Yes
2.8	8.98 ± 0.14	8.10	Yes	Yes	Yes
2.9	7.83 ± 0.14	6.95	Yes	Yes	Yes
3.0	6.20 ± 0.14	5.32	Yes	Yes	Yes
3.1	4.33 ± 0.14	3.45	Yes	Yes	Yes
3.2	3.40 ± 0.14	2.52	Yes	Yes	Yes
3.3	2.60 ± 0.14	1.72	Yes	Yes	Yes
3.4	2.10 ± 0.14	1.22	Yes	Yes	Yes
3.5	1.68 ± 0.14	0.80	Yes	Yes	Yes
3.6	1.64 ± 0.14	0.76	Yes	Yes	Yes
3.7	1.09 ± 0.14	0.21	–	No	Yes
3.8	0.88 ± 0.14	0	No	–	No
3.9	0.70 ± 0.14	-0.18	No	No	–
4.0	0.90 ± 0.14	0.02	No	No	No
4.1	1.22 ± 0.14	0.34	No	Yes	Yes
4.2	1.82 ± 0.14	0.94	Yes	Yes	Yes
4.3	2.54 ± 0.14	1.66	Yes	Yes	Yes
4.4	3.06 ± 0.14	2.18	Yes	Yes	Yes
4.5	5.38 ± 0.14	4.50	Yes	Yes	Yes

Claimed pH range

"Normalized" impurities

PDX-6.23; FOF310. Amneal's expert's (Dr. Marais') analysis also confirmed a statistically significant difference between the claimed range and pH 3.6. FOF316-317.

Real-world evidence supported criticality as well. FOF318. There was a meaningful improvement in stability—a 22% reduction in the impurity appearance rate for Reformulated Vasostrict (spanning the full pH 3.7-3.9 range) relative to Original Vasostrict (pH 3.4-3.6), and a 36% reduction for Reformulated Vasostrict relative to certain of Eagle's registration batches (pH 3.4-3.6). FOF319-321, 326-327, 332. Dr. Kirsch also testified that he analyzed "all of the available room temperature 12-month data" for Reformulated Vasostrict, Original Vasostrict, and Eagle's ANDA product, and "found statistically significant differences between

both the rate of vasopressin lost and the appearance of impurities." FOF328. The inventors and Dr. Kirsch also testified—without any rebuttal by Defendants' experts—how the higher pH of Reformulated Vasostrict provided the real-world advantage of a four-month enhanced room temperature shelf-life compared with Original Vasostrict. FOF323-324; *see also* FOF162-163, 335.

Taken together, Kirsch's statistical analyses of the inventors' experiments and the real-world evidence establish criticality. Moreover, in view of the prior art teachings that a vasopressin formulation would be less stable in the pH 3.7-3.9 range, the stability advantages achieved by the claimed pH range were unexpected. FOF330.

b. Defendants Cannot Rebut Par's Evidence

Defendants' principal attack on Par's evidence is not grounded in case law or common sense. They argue that it is not commensurate in scope with the claimed pH range because Par failed to show any difference in stability between a formulation at pH 3.64 (the highest pH within the 3.4-3.6 range) and a formulation that drifts to pH 3.65 (the lowest pH within the claimed range), and to take it even further to the extreme, where that formulation is 3.65 for only five minutes.[8] DCOL,9-10 (citing *Peterson*, 315 F.3d at 1330).

[8] Defendants' theory is based not on Par's infringement case, but a legal hypothetical asked during cross-examination. FOF185.

This focus on the extreme edge of the claimed range is inconsistent with *In re Peterson*. That case addresses a comparison between the ***claimed range*** and the ***prior art range***: "a prima facie case of obviousness exists when ***the claimed range*** and ***the prior art range*** … are close enough such that one skilled in the art would have expected ***them*** to have the same properties." 315 F.3d at 1329 (emphasis added). Defendants cite no case that focuses on the extreme edges of the claimed and prior art ranges, as opposed to the ranges as a whole. Regardless, Dr. Kirsch testified that there would be a stability benefit in going into the claimed pH 3.7-3.9 range, even for five minutes. FOF334, 336.

Defendants' argument defies common sense. In circumstances where the prior art range partially or entirely encompasses the claimed range—such as pH 3.7-3.9 as against PPC's pH 2.5-4.5—it would be impossible to show criticality. One could never show pH 3.7 is superior to pH 3.7. There is no requirement that the applicant show that every possible embodiment of the claims is superior to every prior art embodiment.

Defendants other criticisms fare no better.

Data Analysis. Defendants contend that Dr. Chyall's review of the "data as a whole" showed only "slight differences in degree." DCOL,11-12.[9] But Dr.

[9] Citing to *Galderma Lab'ys, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 739 (Fed. Cir. 2013), Defendants argue that Par has failed to show a "difference in kind" between

Chyall, who focused on the 25°C data, provided no principled basis for his opinion that there were broad "regions of comparable stability." FOF307-308. He conceded that Dr. Kirsch has "a lot more experience with peptides." FOF309. Dr. Kirsch explained why he (and the inventors) focused on the 40°C data, which showed significant differences. FOF307, 310.[10]

Formulations tested. Defendants are also wrong that Par's criticality evidence is limited to the particular formulations tested. DOL,10. Because pH was a controlled variable in the inventors' pH studies, any differences were attributable to pH. FOF303. Relatedly, Defendants contend that the meaningful improvements for Reformulated Vasostrict relative to Original Vasostrict and Eagle's ANDA product are not attributable to pH because of formulation differences. DCOL,14. But Dr. Kirsch, the only true peptide expert to testify on the issue, explained that those differences are not significant to the stability improvements relative to the differences in pH. FOF331.

---

the claimed range and the prior art. But *Galderma* relates to unexpected results, not criticality. Regardless, as discussed above, the evidence shows such a difference. *See also* FOF313, 321, 324, 327, 329.

[10] Defendants also focus on Dr. Kirsch's testimony that there was no statistically significant difference in impurity formation between the claimed pH range and pH 4.0. This argument fails because Dr. Kirsch explained that 4.0 was unfavorable because it lost vasopressin faster. FOF311.

Stability benefit. Defendants also point to the products' FDA-approved shelf-life and impurity specifications, but that proves nothing about the relative stability of the compositions themselves. DCOL,14. The record evidence showed there was data supporting a longer shelf-life for Reformulated Vasostrict; that Par has not filed to extend the shelf-life (yet) is of no moment. FOF323-325.

In summary, Par presented multiple lines of scientific evidence consistently showing significant differences between vasopressin formulations within the claimed range and those outside it (particularly Original Vasostrict's pH 3.4-3.6 range). That evidence supports criticality, unexpected results, and Dr. Kirsch's overall opinion that the claims are not invalid.

D. Defendants' "Traditional Framework" Argument Is Unavailing

Defendants devote a single paragraph to the obviousness framework required by the Supreme Court.[11] DCOL,18. They had little to work with because Dr. Park did not testify on the *Graham* factors, motivation, or reasonable expectation of success—a fatal flaw in Defendants' obviousness attack. Accordingly, the testimony of Par's *Graham* expert stands unrebutted, as discussed above.

[11] Defendants failed to perform a *Graham* analysis for this Court, relying solely on their flawed presumption theory. It would be manifestly unfair for the Defendants to present a new obviousness analysis to the Federal Circuit, and Par is entitled to an express finding that Defendants did not present a *Graham* analysis.

Indeed, Defendants are merely rehashing their failed anticipation attack, arguing that a POSA would have "adopted" the Original Vasostrict formulation, which would drift into the claimed pH range. The argument relies on unexpected and unknown properties of cherry-picked batches that did not concurrently meet the pH and impurity limitations. FOF293-295. It is no more convincing as an obviousness defense than for anticipation. FOF293-296; *see also* FOF281-282.

III. PAR'S PATENTS ARE ENFORCEABLE

A. Legal Standards

1. Inequitable Conduct

To establish inequitable conduct, Defendants must prove that Par (1) failed to disclose material information or made a material misrepresentation of fact, and (2) did so with a specific intent to deceive the PTO. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011). Each requirement must be proven by clear and convincing evidence. *Id.* If Defendants meet this burden, the Court must weigh the equities to determine whether Par's conduct warrants rendering the entire patent unenforceable. *Id.*

The doctrine originated from Supreme Court cases addressing "particularly egregious misconduct, including perjury, the manufacture of false evidence, and the suppression of evidence." *Id.* Subsequent cases broadening the doctrine had "numerous unforeseen and unintended consequences" and "plagued" the "entire patent system." *Id*. at 1288-89. To stem that tide, *Therasense* "heighten[ed] the

standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." *Id.* at 1290.

The required materiality is "but-for" materiality, necessitating proof the PTO would not have allowed a claim absent the misconduct. *Id*. at 1291. This reflects "basic fairness"—a patent should only be rendered unenforceable "where the patentee's misconduct resulted in the unfair benefit of receiving an unwarranted claim." *Id.* at 1292.

For intent, the specific intent to deceive the PTO "must be the single most reasonable inference able to be drawn from the evidence," and "the evidence 'must be sufficient to *require* a finding of deceitful intent in light of all the circumstances.'" *Id.* at 1290 (citation omitted). Hence, when multiple reasonable inferences may be drawn, "intent to deceive cannot be found." *Id*. at 1290-91.

2. Infectious Unenforceability

For inequitable conduct to infect later-issued patents, there must be an "immediate and necessary relation" between the granting of subsequent patents and the misconduct. *Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 810-11 (Fed. Cir. 1990). This requires more than "mere relatedness of subject matter" (*id.* at 810); there must be "a relation between 'the inequitable conduct that occurred earlier in the chain' of the issued patents and the 'targeted claims of the ultimately-issued patent or patents sought to be enforced.'" *Baxalta Inc. v. Bayer*

Healthcare LLC, 2020 WL 5445375, at *10 (D. Del. July 13, 2020) (citation omitted).

B. Defendants Failed to Prove Inequitable Conduct

Defendants proceeded on two theories: (1) that a declaration submitted during prosecution of the '239 patent to remove the April 2014 Vasostrict Label ("Label") was false; and (2) that declarations submitted during prosecution of the '239 and '478 patents relating to pH studies were also false. Both theories are flawed root and branch—Defendants seek to convert ambiguity into "unmistakable falsity," disregard their burden to establish materiality, lack evidence of intent to deceive, and ignore the stringent requirements for establishing infectious unenforceability.

1. Theory I: Kannan's Inventorship Declaration

Defendants' first theory relates to the alleged falsity of Kannan's November 2015 declaration ("Inventorship Declaration"). There was nothing false in the declaration, no materiality, no intent to deceive anyone, and the declaration bears no relevance to the patents-in-suit.

a. No Falsity

Kannan said he "invented" the "subject matter" of two things: the currently-pending patent claims and the Label. FOF338-340, 352-353. Both statements were true.

An inventor invents the "subject matter" of a claim by identifying a new combination, even though she did not herself invent each individual claim element. *See, e.g.,* 35 U.S.C. §§100(f), (j), 101 (new and useful improvements); *KSR*, 550 U.S. at 418-419 ("[I]nventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known."); *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1361-62 (Fed. Cir. 2004) ("[T]he law requires only that a co-inventor make a contribution to the conception of the subject matter of a claim.").

Accordingly, Defendants do not dispute Kannan's first statement—that he jointly "invented" the "subject matter" of the then-pending claims. FOF352. There is no reason to believe Kannan meant anything different when he said he "invented" the "subject matter" of the Label, for which his contribution was similarly directed to refrigerated storage of vasopressin preparations. FOF338-340, 355. Just as Kannan invented the subject matter of the then-pending claims (the combination of elements recited in the claims as a whole), he also invented the subject matter of the Label (the combination of elements recited in the Label as a whole). FOF353-355, 370.

Defendants argue that Kannan intended instead to convey he had invented each element in the Label individually, but he said no such thing. He testified that

is not what he meant, and the Examiner could not have understood the declaration that way, as she recognized that Par did not invent many of the statements in the Label, such as the use of vasopressin to increase blood pressure. FOF357-359.

Defendants point to the statement in the Interview Summary that the Examiner "recommended" amending paragraph 7 to include a statement that the inventors invented "all of the subject matter relied upon, if possible." DTX-10.1954. But there is no evidence she was referring to inventorship of each element individually, rather than as a combined whole—the way inventorship is normally understood under patent law. FOF353-355, 370. Nor is the Examiner's intent at issue in inequitable conduct.

Par responded appropriately, amending paragraph 7 to include the last two sentences, the first of which added a reference to refrigerated storage—asserted as the primary point of novelty at the time. FOF341-349. The second referred to the invention of the subject matter of the Label but did not use the word "all." Defendants' attempt to shove the word "all" into that sentence, and then expand it to mean "each" element of the Label, would rewrite the declaration. Kannan simply did not make the assertion that he invented every element of the Label individually, and the uncontested evidence is that the Examiner could not have understood it that way. FOF356-359.

b. No Materiality

Kannan's statement that he "invented" the "subject matter of" the Label was immaterial to the '239 prosecution in any event for at least three reasons:

First, under 35 U.S.C. §102(b)(1)(B) (post-AIA), the relevant issue was whether the FDA, who published the Label, "***obtained*** the subject matter" of the Label "directly or indirectly" from the inventors, not whether the inventors had "invented" that subject matter. Defendants did not challenge Kannan's statements that he was an inventor and the FDA obtained the subject matter of the Label indirectly (via Par's Regulatory Department) from the inventors. FOF350-351, 363. Thus, the Label was properly removed as prior art regardless whether Kannan also invented the subject matter of the Label.

Second, the Label disclosed nothing about the degradation products of Vasostrict and was not but-for material to the as-issued claims of the '239 patent. Defendants' inherency position is not supported in the record. FOF345, 364-367, 381.

Third, the relevant disclosures were cumulative of the prior art before the Examiner, including Treschan, Russell, and overlapping pH ranges taught by various references. FOF368; *see supra* II.C.5.a; *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1367 (Fed. Cir. 2008) ("[I]nformation is not material if it is cumulative of other information already disclosed to the PTO.").

c. No Exception to But-For Materiality Applies Here

Defendants argue they need not prove materiality because the Inventorship Declaration was unmistakably false. DCOL,19-21. They are wrong.

Therasense recognized a narrow exception to the "but-for" requirement, which applies when "the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit." 649 F.3d at 1292. The exception reflects earlier Supreme Court cases, "which dealt with 'deliberately planned and carefully executed scheme[s]' to defraud the PTO and the courts." *Id.* (citation omitted). It is intended to apply to "extraordinary circumstances" (*id.* at 1293), and as such, is a narrow exception reserved for "truly extreme misdeeds." *Smith & Nephew, Inc. v. Interlace Med., Inc.*, 955 F. Supp. 2d 69, 73 (D. Mass. 2013); *see also Golden Hour Data Sys., Inc. v. emsCharts, Inc.*, 2012 WL 3494366, *12 (E.D. Tex. Aug. 15, 2012).

No egregious misconduct occurred here. Even if the declaration could be read as meaning something Kannan never intended, it certainly was not ***unmistakably*** false. At worst, there is ambiguity here. FOF352-360.

Scanner Technologies Corp. v. ICOS Vision Systems Corp. N.V., 528 F.3d 1365, 1376-79 (Fed. Cir. 2008), is instructive. The Federal Circuit reversed a finding of inequitable conduct, reasoning that although the challenged statements could be interpreted in a way that made them false, as the district court did, that

was not the only reasonable interpretation. *Id.* Numerous district courts have held that ambiguities in allegedly false statements precluded a finding of inequitable conduct. *Smith & Nephew*, 955 F. Supp. 2d at 73; *Sightsound.com Inc. v. N2K*, 391 F. Supp. 2d 321, 362-366 (W.D. Pa. 2003); *Go Medical Indus. Pty., Ltd. v. Inmed Corp.*, 300 F. Supp. 2d 1297, 1309-12 (N.D. Ga. 2003); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 348 F. Supp. 2d 713, 744-45 (N.D.W.V. 2004).

In *Smith & Nephew*, the court held that "the ambiguous misrepresentations here simply do not present the 'extraordinary circumstances' of affirmative egregious misconduct," despite finding that the inventor's description of his invention "is certainly somewhat misleading," that he "would have been better advised" to describe his invention "more carefully," and that his statements could have misled a reader. 955 F. Supp. 2d at 73. *See also Go Medical*, 300 F. Supp. 2d at 1309-10 (rejecting attempt to "adopt an overly narrow definition of the word 'discovered' and ignore the context in which the word was used.")

Defendants' reliance on *Intellect Wireless, Inc. v. HTC Corp.*, 732 F.3d 1339 (Fed. Cir. 2013) (DCOL,21), is illuminating, as it shows the type of conduct the exception is really designed to address. It was undisputed that the inventor's declaration was "unmistakably false" in claiming the creation and demonstration of a "working prototype" cell phone, which in fact was a non-working "imitation" that did not practice the invention. *Id*. at 1342-44. The inventor told numerous,

bald-faced lies he could not have believed were true. That is what "unmistakable falsity" looks like.

This is simply not an unmistakable falsity case. Properly understood, the Inventorship Declaration is truthful; at worst, it is subject to ambiguity and could have been drafted with greater precision. But lack of clarity is not inequitable conduct.

d. No Intent to Deceive

To establish the requisite intent, the evidence "must be sufficient to *require* a finding of deceitful intent in light of all the circumstances." *Therasense*, 649 F.3d at 1290 (citation omitted). When multiple reasonable inferences may be drawn, "intent to deceive cannot be found." *Id*. at 1290-91. "A finding that the misrepresentation or omission amounts to gross negligence or negligence under a 'should have known' standard does not satisfy this intent requirement." *Id.* at 1290.

Defendants fail to apply this standard, citing pre-*Therasense* caselaw muddling the materiality and intent elements to lessen their burden (*see* DCOL,29-31), but this is error. *Therasense*, 649 F.3d at 1290 (courts may not use a "sliding scale" or "infer intent solely from materiality"). Indeed, *Therasense* expressly rejected Defendants' assertion and case law (DCOL,29-30) that intent to deceive

can be found based solely on the alleged lack of a "credible explanation" for the declaration (which exists here in any event). *Id.* at 1291.[12]

There is simply no basis for concluding that the only possible inference here is deceit. Kannan explained in detail why he believed his declaration was truthful, and cross-examination poked no holes in his convictions. FOF356. His testimony, which was unrebutted, defeats Defendants' charge of intent to deceive.

Defendants try to fill the hole in their proofs by asserting that "both Kannan and Kenesky" understood the Examiner "required" that the inventors invented "all" of the subject matter of the Label. DCOL,30. But there is no evidence Kannan was aware of the interview, and Defendants grossly misstate the record. All the Examiner actually said was that she "recommended" Par provide such a declaration "if possible." FOF348, 370. By "all," the Examiner could not have meant a certification the inventors invented each element individually–including the invention of vasopressin to raise blood pressure. FOF357-359. Most importantly, the Examiner would have seen that Par did not use the phrase "all the subject matter" in the declaration. FOF349. Par responded truthfully to the

[12] Defendants likewise misstate current law in asserting it is "legal error" to focus on Kannan's actual state of mind (DCOL,29), as *Therasense* made clear that specific intent to deceive requires deliberate and knowing misconduct. *Id.* at 1290.

Examiner's comments, never asserting that Kannan had invented each element in the Label. FOF369-370.

e. No Immediate and Necessary Relation

Defendants try to gloss over the fact that there is no "immediate and necessary" relation between the alleged flaw in the Inventorship Declaration and the patents-in-suit. The declaration removed the Label as prior art to the '239 patent, but it is prior art to the '209 and '785 patents—indeed, it discloses pH 3.4-3.6, already believed to be optimized in the art. Moreover, Par told the PTO that the claims of the '785 and '209 patents were "narrowly drawn around the results of Examples 14 and 15 in the specification," which were disclosures added after-the-fact to those patents and not found in the '239 patent. And the parties agree the patents-in-suit are not entitled to claim priority back to the '239 patent. FOF371-380. There is simply no connection between the Inventorship Declaration and the patents-in-suit.

In short, Defendants tried the unenforceability of a patent that is not in-suit, regarding an issue that is immaterial to the actual patents-in-suit. All Defendants really point to is that the patents share some common disclosures, but that is insufficient under the law to establish infectious unenforceability. *Power Integrations, Inc. v. Fairchild Semiconductor International, Inc.*, 2009 WL 4928024 at *9 (D. Del. Dec. 18, 2009), *report and recommendation adopted* 2010

WL 2990039 (D. Del. July 10, 2010) (dismissing inequitable conduct claim even though the "specifications are related and share some figures," and "many of the claims of each patent include substantively the same limitations").

2. Theory II: Kannan's pH Declarations

Defendants' second theory challenges the accuracy of two declarations discussing pH study data, Kannan's March 2016 and May 2017 declarations (the "pH Declarations"). These declarations were truthful, there was no materiality or intent to deceive, and there is no "immediate and necessary relation" between these declarations and the patents-in-suit.

a. Prosecution of the Patents-in-Suit

The applicant submitted the pH Declarations during prosecution of the '478 and '239 patents—not the patents-in-suit. FOF382-395, 435. During prosecution of the '209 and '785 patents, the applicants argued patentability based on data and information described in Example 15 and elsewhere in the specification of those patents. FOF382-388, 431-438. Par explained that "[t]he present claims are narrowly drawn around the results of Examples 14 and 15 in the specification," which describe 15-month stability data obtained on Par's Reformulated Vasostrict product that were not included in the disclosures for '239 or '478 patents. FOF384-385.

b. No Falsity

During prosecution of the ’478 patent, Par submitted a pH study comparing the impact of pH on stability over the range pH 3.5-4.5. Because the prior art PPC reference disclosed pH 2.5-4.5, the Examiner requested data for the lower part of that range (2.5–3.4). Par performed the additional study and presented combined data in three forms: (1) tabular numerical data showing assay and impurity levels, (2) graphs plotting measured impurity values after 4 weeks, and (3) graphs plotting the calculated % decrease in assay values after 4 weeks. FOF402-408.

The Examiner noticed a “break” in the data between pH 3.4 and 3.5 where the two studies were joined, for both the measured impurity values and the calculated change in assay values, and requested information about whether that was the result of differences in how the studies were conducted. FOF394. In response, Kannan provided a declaration explaining in painstaking detail how the second study was performed in the same way as the first, including extensive steps taken to control for test conditions, formulation components, and other input variables. FOF395-401.

After providing those details, Kannan explained that Figures 5-6 (of his May 2017 declaration) provided “direct comparisons of the % total impurities observed” in the two studies. The Figures plotted “% Total Impurities” against pH. Neither the chart, nor the accompanying discussion, state that the impurity data had been

normalized (i.e., modified) in any way. These Figures simply plotted the raw data resulting from the measured test outputs. FOF403, 407.[13]

In contrast, in the next paragraph, Kannan explained that Figures 7-8 provide "normalized plots comparing the assay [values]." FOF404, 406. The Figures plotted "% Assay Decrease (Absolute)" against pH. A percentage decrease from a starting point is inherently normalized because it reflects calculated values based on the measured raw data. This is all second-nature to formulation scientists, and the fact that the total impurities data plots were not normalized, but the assay value plots were, is readily apparent to a POSA both from the Figures themselves and from a comparison of the plots to the raw data. *See* FOF402-408.

Defendants nevertheless contend Kannan misrepresented the total impurities plots as having been normalized when he said in paragraph 32 that "as described above…pH was the only variable not normalized." DTX-10.2369; FOF409.

There was no misrepresentation. Defendants are conflating normalized plots/data with normalization of variables. FOF409-412. The former relates to the way data obtained in a study (i.e., measured outputs) are presented, as with the "normalized plots" of assay values in Paragraph 30. The latter relates to the

[13] For brevity, Par addresses Defendants' arguments in the context of the May 2017 Declaration. Those responses apply with equal force to the March 2016 Declaration.

control of differences in test conditions/inputs, as described in Paragraphs 24-28. FOF410-411.

Paragraph 32 was the concluding paragraph setting forth Kannan's ultimate conclusions regarding the impact of pH on assay and total impurities values. He referred to his description "above" detailing how Par had diligently replicated the test procedures in the two studies, changing only pH. FOF395-401, 409-414. That is what Kannan meant when he said "[a]s described above," pH was the "only variable" not normalized. *Id*. The statement was true.

There is no evidence suggesting the Examiner misunderstood these points and believed Kannan was representing that Figures 5-6 were normalized plots of total impurities, particularly because (1) he specifically described Figures 7-8 (the assay plots), but not Figures 5-6, as "normalized plots," and (2) the y-axis labels and raw data itself made clear that Figures 5-6 were not normalized plots. FOF402-408.

c. No Materiality

The discussion above in Sections III.B.1.b-1.c concerning the materiality of declarations applies equally here. This is not a situation in which unmistakably false data was presented to the PTO.

Defendants rely heavily on *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556 (Fed. Cir. 1983), which predates *Therasense* by 28 years and reflects the

standard of a different time. The patentee submitted knowingly falsified data, and it could not "be said that these misrepresentations to the PTO were the result of an honest mistake." *Id.* at 1570-71. Here, Par provided the raw data and plots of that data. Regardless of any confusion surrounding the impurity graphs, there is no parallel to *Rohm & Haas*, where the submitted data were falsified. *Id.* at 1570. Indeed, every witness agreed that the differences between the non-normalized and normalized impurity plots would have had no impact on evaluating the criticality of pH 3.7-3.9. FOF415-427. It would be perverse to render a patent unenforceable due to a possible mistake in the presentation of truthful data that had no bearing on patentability.

d. No Intent to Deceive

Kannan credibly testified that he believes his declarations were true and provided a credible explanation for what he meant by the allegedly false statement (FOF409-414) and that his conclusions about the impact of pH would not have changed regardless whether he presented normalized or non-normalized impurity plots. FOF415-427. And the science underlying the latter assertion was confirmed by both Dr. Kirsch and Dr. Chyall. FOF415-416, 420-427. Indeed, Dr. Chyall conceded he could not discern any evidence of intent to deceive based on the content of the declarations or underlying data. FOF428-430. Given that intent to deceive must be the only reasonable inference, that admission is dispositive.

e. No Immediate and Necessary Relation

As discussed above, the challenged declarations were not filed during prosecution of the patents-in-suit, the claims of which were "narrowly drawn" around the data from Examples 14 and 15. FOF382-388, 431-438. Moreover, in arguing patentability, Par also cited the 40ºC impurity plot to confirm the criticality of the claimed pH range, and everyone agrees that plot is not materially different from the normalized 40ºC plot. FOF415-427. There is no evidence that ties the presentation of non-normalized impurity plots, or Kannan's statements about normalization, to the patentability of the asserted patents.

C. A Finding of Unenforceability Would be Inequitable

Ultimately, even if the elements of inequitable conduct are established, the court must weigh the equities. *Therasense*, 649 F.3d at 1287. Here, there would be no equity in finding unenforceability. At best, Defendants have identified two ambiguous statements on matters that bear no relationship to the patents-in-suit. There is no evidence Par received an unwarranted benefit from the accused conduct, and so a finding of inequitable conduct would not right a wrong but create a windfall for Defendants. That is not equity, and the Court should decline to render a sentence of capital punishment against the asserted patents.

IV. CONCLUSION

Par respectfully submits that the Court should find that Defendants failed to prove the patents-in-suit either invalid or unenforceable.

Dated: July 28, 2021

Respectfully submitted,

FARNAN LLP

/s/ Michael J. Farnan
Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 North Market St.
12th Floor
Wilmington, DE 19801
Tel: 302-777-0300
Fax: 320-777-0301
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Plaintiffs Par Pharmaceuti
Inc., Par Sterile Products, LLC, and End
Par Innovation Company, LLC

OF COUNSEL:

Martin J. Black
Sharon K. Gagliardi
Brian M. Goldberg
Luke M. Reilly
Daniel R. Roberts
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104
Tel: (215) 994-4000
martin.black@dechert.com
sharon.gagliardi@dechert.com
brian.goldberg@dechert.com
luke.reilly@dechert.com
daniel.roberts@dechert.com

Robert D. Rhoad
DECHERT LLP
502 Carnegie Center, Suite 104
Princeton, NJ 08540-7814
Tel: (609) 955-3200
robert.rhoad@dechert.com

Jonathan D. J. Loeb, Ph.D
DECHERT LLP
2400 W. El Camino Real, Suite 700
Mountain View, CA 94040-1499
Tel: (650) 813-4995
jonathan.loeb@dechert.com

Blake B. Greene
DECHERT LLP
300 W. 6th Street, Suite 2010
Austin, TX 78701
Tel: (512) 394-3000
blake.greene@dechert.com

CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of the Court's November 6, 2019 Standing Order. The text of this document was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, this document contains 7,483 words, excluding letterhead, captions, and related non-substantive portions, compliant with the Court's limitations set forth at the close of trial. Trial Tr. 917:16-20.

/s/ Michael J. Farnan

Michael J. Farnan

Dated: July 28, 2021